

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/562,634 | 12/29/2005 | Tsuyoshi Yamagata | 00005.001282 | 7646 |
| 5514 7590 09/14/2007 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA | | | EXAMINER | |
| | | | SIMMONS, CHRIS E | |
| NEW YORK, NY 10112 | | | ART UNIT | PAPER NUMBER |
| | * | | 1614 | |
| | | | | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/14/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | | | |
|--|--|---|--|--|--|--|--|
| | | 10/562,634 | YAMAGATA ET AL. | | | | |
| • | Office Action Summary | Examiner | Art Unit | | | | |
| | | Chris E. Simmons | 1614 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | | |
| WHIC - Exter after - If NO - Failui Any r | PRIENT STATUTORY PERIOD FOR REPLY HEVER IS LONGER, FROM THE MAILING DA sisions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. period for reply is specified above, the maximum statutory period we to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 2a) <u></u> □ | Responsive to communication(s) filed on <u>29 De</u> This action is FINAL . 2b) This Since this application is in condition for allowar closed in accordance with the practice under E | action is non-final. nce except for formal matters, pro | | | | | |
| Dispositi | on of Claims | | | | | | |
| 5) 6) 7) | Claim(s) 1-3,7-9,13,14 and 16-22 is/are pendir 4a) Of the above claim(s) is/are withdray Claim(s) is/are allowed. Claim(s) is/are rejected. Claim(s) is/are objected to. Claim(s) 1-3,7-9,13,14 and 16-22 are subject to | wn from consideration. | rement. | | | | |
| Applicati | on Papers | | | | | | |
| 10) | The specification is objected to by the Examine The drawing(s) filed on is/are: a) accomplicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Example 1. | epted or b) objected to by the drawing(s) be held in abeyance. Settion is required if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | | |
| Priority (| ınder 35 U.S.C. § 119 | • | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | | | | | |
| 2) Notice 3) Information | t(s) te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) tr No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other: | ate | | | | |

Art Unit: 1614

DETAILED ACTION

Status of the claims: Receipt is acknowledged of the preliminary amendment filed 12/29/2005. Accordingly, claims 3, 7, 9, 13, 16, 18-19, and 21 are amended, claims 4-6, 10-12, and 15 are cancelled, and claim 22 is newly added. Claims 1-3, 7-9, 13-14, and 16-22 are presented for examination.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3 and 16-18, drawn to composition comprising the compound of Formula I and an alpha-1-adrenergic agent and a pharmaceutically acceptable carrier. Please see further specie election requirement outlined below.

Group II, claim(s) 7-9, drawn to a kit comprising the compound of Formula I.

Please see further specie election requirement outlined below.

Group III, claim(s) 13-14, drawn to the compound of formula I.

Group IV, claim(s) 19-22, drawn to a method of treating bladder irritative symptoms. Please see further specie election requirement outlined below.

Art Unit: 1614

The inventions listed as Groups I to IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature is not a special technical feature a posteriori because the common technical feature is not the Applicants' contribution over the prior art. The common technical feature in Groups I to IV is the compound of formula I having the CAS Registry Number 214764-26-8. However this compound was disclosed in the American Chemical Society's chemical database on November 25, 1998.

Specie election

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specific alpha-1-adrenergic compound that is encompassed by the claims.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. In order to be completely responsive to this species election requirement, Applicants must further elect a specific alpha-1-adrenergic compound (e.g., tamsulosin, prazosin, terazosin, etc.). The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Art Unit: 1614

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-3, 7-9, and 16-22.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the common technical feature is not a special technical feature a posteriori because the common technical feature is not the Applicants' contribution over the prior art.

Joint Inventors

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

70011(10114d11)bC1: 107002,00

Art Unit: 1614

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chris E. Simmons whose telephone number is (571) 272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1614

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Chris Simmons
Patent Examiner
AU 1614

September 4, 2007

SUPERVISORY PATENT EXAMINER

